REMARKS:

Claims 1-6, 8-10 and 24-31 remain pending.

Applicant notes with appreciation the retraction of the previous Section 112 rejection.

Pursuant to the Examiner's request (page 4, second paragraph of the Final Rejection), applicant has amended the specification by summarizing the claims to provide the requested antecedent support for the claimed subject matter. Applicant believes he has done so and requests that the Examiner accept the proposed additions to page 7 of this application.

Attached hereto is the Declaration of Ronald W. Smith Pursuant to 37 CFR 1.132 (the "Smith Declaration").

Substantively, all claims continue to be rejected for anticipation or obviousness over the Cohen patent. In applicant's most recent Amendment dated April 30, 2001, applicant argued at length why the pending claims are neither anticipated by nor obvious over Cohen. These arguments are not being repeated herein.

However, the Final Rejection, in its "Response to Arguments" section on pages 5-7 of the Final Rejection, includes a number of new arguments which are addressed herein.

On page 6 of the Final Rejection, applicant's Declaration dated April 19 and filed May 4, 2001 (the "earlier Declaration") was considered deficient in that it only refers to the "system described in the above-referenced application and not to the individual claims of the application" and that "there is no showing that the opinion evidence of nonobviousness is commensurate in scope with the claims". Reliance was placed on MPEP §716, and in particular the "opinion evidence" addressed in §716.01(c).

The earlier Declaration was submitted to explain what the Cohen patent does and does not disclose to one of ordinary skill in the art, and it addresses certain attributes the Examiner assigned to the disclosure of Cohen. The earlier Declaration further states (page 5, sixth and seventh lines from the bottom) that the implant of the present invention permits "slidable motion between the face and the first joint surface", as recited in claim 1, line 10, which is not possible with Cohen's implant. Thus, contrary to the assertion in the Final

Rejection, the earlier Declaration does demonstrate why and how the claims are nonobvious over Cohen.

Further, the earlier Declaration is not an expert declaration and does not address the advantages of the claimed invention over the prior art. Rather, it sets forth what the Cohen patent fairly teaches one of ordinary skill in the art. Under such circumstances, it is inappropriate to hold that since the Declaration was by the inventor, its significance is somehow reduced.

In paragraph (8) on page 7 of the Final Rejection, the Examiner disagrees with applicant that "joint fusion" is the goal of Cohen and took the position "that the opposite is true". Under no circumstances can sliding surfaces be formed by the fibrous tissue that forms between the resected bone ends of Cohen that are spaced apart by ball (4). Physiological sliding surfaces do not and cannot be formed by fibrous tissue alone as it forms unless the fibrous tissue grows against and is movable relative to a separate surface. Cohen has no such separate surface. ("Supplemental Declaration" of Gerald Blatt dated August 27, 2001 and attached hereto, paragraph bridging pages 1 and 2.)

Likewise, the Smith Declaration states in relevant parts that no sliding surface is or can be formed by the fibrous tissue that grows between the resected bone ends of Cohen, because implants which have stems that penetrate into the bones do not and cannot develop a functional gap that permits articular motion. The "solid" rods of the Cohen patent that project from the central spacer and extend into drilled holes in the opposite bone ends prevent slidable motion between the face of the implant and the opposing surface of the cancellous bone, including any fibrous tissue that may form thereon, thereby also preventing the generation of any surface by the fibrous tissue that can accommodate relative slidable motion. The Cohen implant leads to the formation of a continuous fibrous tissue body that extends from one bone end to the other, opposite bone end. This is in marked contrast to the implant without stems developed by Dr. Blatt, which permits articular motion at the joint, resulting in slidable motion between the face of the implant and the opposing bone surface and fibroplast growing thereon. (Smith Declaration, page 4, first and last full paragraphs.)

As is described by Cohen (column 2, lines 26-29), the "metatarsal implant of a biodegradable substance [namely ball 4 implanted between the resected bone ends] ... would eventually be replaced by mature fibrous tissue". Cohen further states (column 2, lines 45-47) that "over time, fibrous tissue extends around the implant, and replaces the implant, which is eventually absorbed into the body". This constitutes an unequivocal and correct description of the physiological process that takes place in Cohen, namely the growth of a continuous body of fibrous tissue that extends from the resected end of one of the bones to the resected end of the other bone. The desired end result is a fusion of the joint, which is the antithesis of motion. (Supplemental Blatt Declaration, page 2, first full paragraph; Smith Declaration, paragraph bridging pages 3 and 4.)

Applicant further disagrees with the following arguments advanced in the Final Rejection of July 12, 2001 because they are wrong for being contrary to well-established medical knowledge and physiological facts:

- "Next, Applicant argues that no slidable joint movement is possible with the Cohen devices. However, the Examiner respectfully disagrees and maintains that column 4, lines 38-39 explicitly states that the joint can flex after implantation of the implant. The Examiner cannot interpret the language different from what it explicitly states. *For this reason, a slidable movement over the spacer is clearly provided.*" (Final Rejection, page 5, first full paragraph.)

In Cohen, movement of the spacer is clearly **not** provided. The italicized portion of the quotation from the Final Rejection is contrary to and ignores medical knowledge and physiological facts. (Supplemental Blatt Declaration, page 2, second to fourth full paragraphs.)

The Smith Declaration explains in more detail why the spacer or implant of Cohen is not slidable relative to the bone or the fibroplast/fiber cartilage growing on the bone. As stated above, no sliding surface is or can be formed by the fibrous tissue that grows between the resected bone ends of Cohen, because implants which have stems that penetrate

into the bones do not and cannot develop a functional gap that permits articular motion. The "solid" rods of the Cohen patent that project from the central spacer and extend into drilled holes in the opposite bone ends prevent slidable motion between the face of the implant and the opposing surface of the cancellous bone, including any fibrous tissue that may form thereon, thereby also preventing the generation of any surface by the fibrous tissue that can accommodate relative slidable motion. The Cohen implant leads to the formation of a continuous fibrous tissue body that extends from one bone end to the other, opposite bone end. This is in marked contrast to the implant without stems developed by Dr. Blatt, which permits articular motion at the joint, resulting in slidable motion between the face of the implant and the opposing bone surface and fibroplast growing thereon. (Smith Declaration, page 4, first and last full paragraphs.)

Further, as already stated in the earlier Declaration, the statement in Cohen that "flexion and extension of the joint should not result in dislocation of the implant" (column 2, lines 38-39) means and can only mean that when the patient flexes or extends the toe as a whole, the resulting forces applied to the implant should not result in its dislocation. In other words, the implant must be capable of withstanding such forces, thereby preventing motion and enabling a fusion of the bones by growing the above-mentioned continuous body of fibrous tissue between them. (Supplemental Declaration, paragraph bridging pages 2 and 3.)

- In response to the assertion that joint fusion is a goal of Cohen, *the Examiner respectfully disagrees and takes the position that the opposite is true.* Column 2, lines 37-44 explain that the gap of 1 mm or more is to prevent "growth of bone" (i.e. bone fusion) between the bone ends. *The Examiner asserts that this gap leads to an articulating joint.* (Final Rejection, page 5, last full paragraph.)

The Examiner's position and assertions as set forth in the italicized portions of the quotation are unsupported by Cohen, ignore medical knowledge, and are contrary to physiological facts. Further, the formation of an articulating joint is not Cohen's intent and, more importantly, is not possible with the procedures disclosed in the Cohen patent for the

reasons stated in this and my earlier Declaration. (Supplemental Declaration, page 3, first and second full paragraphs; Smith Declaration, page 4, third to fifth paragraphs.)

- With regard to the argument that sliding motion is prevented by Cohen, the Examiner respectfully disagrees and takes the position that since the joint can flex and extend with the implant in place (see Col. 4, lines 38-39) such that [sic] *slding on the ball (4) face would inherently occur*. (Final Rejection, page 6, first sentence of subparagraph (5).)

The Examiner's position as set forth in the italicized portion of the quotation is contrary to medical knowledge and physiological facts. (Supplemental Declaration, page 3, third and fourth full paragraphs; Smith Declaration, page 2, fourth paragraph, to page 4, first full and last paragraphs.)

Applicant's Supplemental Declaration and the Smith Declaration specifically address the Examiner's arguments discussed above and demonstrate that they are contrary to fact and medical knowledge.

For example, the Cohen reference correctly and unequivocally states that the implant consists of a ball and solid rods, yet the Examiner disregards this language and maintains that the implant does permit flexing. Equally, the Examiner entirely disregarded applicant's explanation of what the sentence "flexion and extension of the joint should not result in dislocation of the implant" means, as set forth in the earlier Declaration (page 3, last paragraph, to page 4, second full paragraph) and Supplemental Declaration (paragraph bridging pages 2 and 3 thereof).

On another point, the Examiner disagrees that fusion is the goal of Cohen and maintains that "the gap of 1 mm or more is to prevent 'growth of bone' (i.e. bone fusion) between the bone ends. The Examiner asserts that this gap leads to an articulating joint." This observation is squarely contrary to what Cohen discloses and teaches one skilled in the art. It is also contrary to what in fact happens. (Smith Declaration, page 2, fourth paragraph; page 3, first and second full paragraphs; paragraph bridging pages 3 and 4; and pages 4 and 5, first paragraph.) Rather, it is speculation that this gap "leads to an articulating joint", speculation

which is nowhere supported by anything in the Cohen reference and diametrically opposed to the knowledge and experience of those skilled in the art, such as the applicant and Dr. Smith.

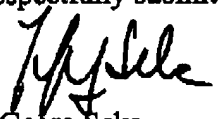
In fact, what distinguishes the present invention as defined in the independent claims (which all require "slidable motion" between the implant face and the opposing joint surface) is that the implant used in the method of the Blatt application has a face that is free to slide relative to the opposing, cancellous bone surface, and fibrous tissue growing thereon, because there is no stem that extends from the implant face into the opposing bone. This leads to the formation of a fibrocartilage surface that permits painfree slidable motion between the face of the implant and the opposing surface of the bone. This cannot be achieved with the Cohen implant.

In sum and substance, applicant again submits that the rejection of the claims over Cohen, for anticipation or obviousness, is improper. At best, the rejection is based on an impermissible hindsight reconstruction of the prior art based on what is disclosed in the present application, which can never form the basis for rejecting any claim.

Accordingly, applicant again urges reconsideration of the rejection and an allowance of all claims at an early date.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



J. Georg Seka
Reg. No. 24,491

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
JGS:jhw
SF 1293285 v1

MARKED-UP VERSION OF THE CHANGES TO THE SPECIFICATION

Page 7, paragraph beginning at line 8:

[The] Referring to Figs. 2 and 3A-3F, the present invention is directed to a method for treating a joint surface, typically an arthritic joint surface, which uses a bioresorbable implant, such as implant 23, configured for positioning between [articular] articulated joint surfaces such as the opposing surfaces of a hand (finger) joint or a shoulder joint, e.g. between a surface 20 and a resected surface 34. At [at] least one of the joint surfaces, e.g. resected surface 34, is [being] an exposed cancellous joint surface[, and a method for treating a joint surface, typically an arthritic joint surface].

The method of the present invention is therefore for treating at least one of two opposing, first and second, relatively movable joint surfaces by initially resecting the bone to form a cancellous bone surface. A bioresorbable implant, such as implant 23, is placed between the first and second surfaces to space them apart. The implant has at least one face which is opposite and shaped complementary to the opposing bone surface so that the implant can slidably move relative to the at least one of the first and second surfaces. By allowing the face of the implant to slidably move relative to the resected surface while promoting the growth of fibroblast on the cancellous surface for a sufficient time to allow the fibroblast to convert into fibrocartilage, the fibrocartilage generates a fresh, sliding joint surface. The implant maintains a spacing between the joint defining surfaces, and after the implant has resorbed, the fibrocartilage defines the joint surface.

The invention has been tested through an animal study, described below.